DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

WARNING LETTER
SJN-01-06

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

January 19, 2001

Omar Martinez Torres
Executive Director
Bella Vista Hospital Blood Bank.
P.O. Box 1750
Mayaguez, PR 00681

Dear Mr. Martinez:

From December 13 to 28, 2000 an investigator from our office conducted an inspection of your unlicensed hospital blood bank located at Road # 349, Cerro Las Mesas, Mayaguez, PR. The investigator documented deviations from the Current Good Manufacturing Practices (GMP's) for Blood and Components, Title 21, Code of Federal Regulations, part 606 (21 CFR 606), General Biological Products Standards (21 CFR 610) and Additional Standards for Human Blood and Blood Products (21 CFR 640). These deviations cause the Blood and Blood products manufactured and tested by your firm to be adulterated within the meaning of section 501 (a) (2) (b) of the Food Drug and Cosmetic Act (the Act).

The deviations reported were as follows:

1. Failure to restrict the use of blood that tested positive for hepatitis B surface antigen as required by 21 CFR 610.40 (c) & (d) in that:

   Red Blood Cells from Whole Blood unit # 018585, which was initially reactive for HBC antigen, were transfused to a patient in the hospital on 12/5/99. The unit was subsequently tested and found to be reactive for HBC by confirmatory test on 12/10/99.

2. Failure to have adequate crossmatch testing controls to assure that units of correct group and type are issued to recipients as required by 21 CFR 606.151. For example:

   Unit # 54KF91822 of "O positive" Red Blood Cells was transfused to a recipient with an "O negative" group & type on 8/11/99. Investigation into the incident found the technologist performing the crossmatch failed to test the recipient's sample for group and type and/or failed to check the previous crossmatch records for the same recipient.

3. Failure to follow Standard Operating Procedures for the testing and storage of Whole Blood and components as required by 21 CFR 606.100. For example:

   The SOP entitled Procesamiento De Las Pintas De Sangre Para Ser Transfundidas (Processing of Blood Units for Transfusion) requires that units which test initially reactive for one or more viral marker tests be placed in biohazard bags on a separate shelf of the blood storage refrigerator which is marked with the sign, "blood without testing". This procedure was not followed for unit # 018585, discussed in #1 of this letter.

   The same SOP also requires that the donor-testing logbook be checked by a second medical technologist prior to labeling. This step also was not performed for unit # 018585.

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the address on the letterhead above to the attention of Mary L. Mason, Compliance Officer.

Sincerely,

Mildred R. Barber

Mildred R. Barber
District Director

CC: Gerardo Latoni, M.D.
Blood Bank Medical Director
Bella Vista Hospital Blood Bank